UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,730	03/28/2006	Vladimir Pekar	PHUS030326US	2262

38107 7590 05/22/2009

PHILIPS INTELLECTUAL PROPERTY & STANDARDS
P. O. Box 3001
BRIARCLIFF MANOR, NY 10510

EXAMINER	
HARRIS, CARRIE R	

ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
05/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,730	PEKAR ET AL.	
	Examiner	Art Unit	
	Carrie Harris	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *28 March 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. **Claims 1-7 and 14-16** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. In particular, claims 1 and 14 are drawn to a process. Under 35 U.S.C. 101 a process must 1) be tied to another statutory class (such as a particular apparatus) or 2) transform underlying subject matter (such as an article or materials) to a different state or thing. The claimed process steps do not transform underlying subject matter. Thus, to qualify as a 35 U.S.C. 101 statutory process, the claims should positively recite the other statutory class (apparatus or thing) to which it is tied, for example by identifying the apparatus that accomplishes the method steps.

In this case, the "method of planning a radiation therapy" and the "method for adapting a dose distribution of a radiation therapy plan" are not sufficiently tied to another statutory class. In fact, claim 1 is lacking of any structural details to perform the process of determining a dose distribution on the basis of an image, determining at least one of the shape and position variation of an object in an image, and adjusting the dose distribution. Claim 2 is also lacking of any structural details to perform the process of adapting first surface mesh, adapting a second surface mesh, and deforming a volumetric model. Furthermore, regarding claims 2-6 and 15-16, the process steps

recited in these claims are not sufficiently tied to another statutory class. The claims are lacking of any structural details to positively tie the image processing algorithm claimed to an apparatus.

Additionally, since no subject matter (i.e. article or structure) was claimed there is no physical transformation to a different state or thing.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 1-16** are rejected under 35 U.S.C. 102(b) as being anticipated by Di Yan et al., "A Model or Accumulate Fractionated Dose in a Deforming Organ". International Journal of Radiation Oncology, Biology, Physics 44.3 (1999): 665-675.

Regarding **claim 1**, Di Yan et al. teaches a method of planning a radiation therapy, the method comprising the steps of: determining a dose distribution for a target volume on the basis of a first image (CT image obtained prior to treatment for planning, p.666, col. 2, paragraph 2; p. 669, col. 1, paragraph 3); determining at least one of shape and position variation of an object of interest in the target volume between the first image and a second image (reference image is the planning CT image, and organ motion at each treatment fraction is calculated with respect to the original planning position, page 666, column 2, paragraph 2); and adjusting the dose distribution on the

basis of the at least one of shape and position variation (total dose, D(v), depends on the calculated organ displacement, p. 669, col. 1, paragraph 1); wherein the first and second images where taken at different points in time of a radiation treatment process (planning CT image is a first image, and image at a fraction treatment is a second image taken at different points in time, p. 666, col. 2, paragraph 1).

Regarding **claim 2**, Di Yan teaches the steps of: applying a first surface mesh to the object of interest in the first image (reference image mesh, p. 667, col. 1, paragraph 1); performing a first adaptation of the first surface mesh to a surface of the object of interest in the first image resulting in a second surface mesh (generating and applying a surface mesh necessarily includes adapting a surface mesh to an object of interest in the image, p. 667, col. 1, paragraph 1); applying the second surface mesh to the object of interest in the second image (second image is k treatment CT image that is analyzed with the same volumetric mesh procedure as the first image, p. 668, col. 2, paragraph 1); performing a second adaptation of the second surface mesh to the surface of the object of interest in the second image resulting in a third surface mesh (generating and applying a surface mesh necessarily includes adapting a surface mesh to an object of interest in the image, p. 667, col. 1, paragraph 1; second image is k treatment CT image, p. 668, col. 2, paragraph 1); and obtaining a difference between the second surface mesh and the third surface mesh (difference between volumetric meshes is the displacement calculated in three dimensions as vector U, p. 668, col. 1, paragraph 3).

Regarding **claim 3**, Di Yan et al. teaches the steps of: generating a volumetric model of the object of interest on the basis of the second surface mesh (second

volumetric mesh is necessarily a volumetric model derived from the k treatment CT image and the volume mesh, p. 667, col. 1, paragraph 1; p. 668, col. 2, paragraph 1); and deforming the volumetric model on the basis of the difference resulting in a deformed volumetric model (calculates displacement and new position of the organ based on a subsequent image, which is volumetric organ deformation, p. 668, col. 1, paragraph 3).

Regarding **claim 4**, Di Yan et al. teaches that the difference is used as a boundary condition for the deformation of the volumetric model (iteratively solving the system of linear equations necessitates establishing boundary conditions for each iterative step, which is the displacement solution for the previous mathematical step p. 668, col. 1, paragraph 2).

Regarding **claim 5**, Di Yan et al. teaches that the shape and position variation of the object of interest is determined on the basis of the deformed volumetric model (organ deformation is calculated, which is necessarily shape and position variation of the organ because the deformation is changes in position of volume nodal centroids in three dimensions, p. 667, col. 1, paragraph 1; p. 668, col. 1, paragraph 2).

Regarding **claim 6**, Di Yan et al. teaches a biomechanical model is taken into account for the deformation of the volumetric model (Hooke's law and Newton's laws were used to generate the biomechanical model, p. 667, col. 1, paragraph 1).

Regarding **claim 7**, Di Yan et al. teaches that the first and second images are computed tomography (CT) images (first image is the reference image, and the second image is taken at a subsequent ith day of treatment by CT, Abstract; p. 666, col. 2,

paragraph 1; first image is CT planning image, second image is kth treatment image, p. 668, col. 2, paragraph 2).

Regarding **claims 8-10**, Di Yan et al. teaches a radiation therapy planning device, comprising: a memory for storing a first image and a second image (CT images are taken as the input data to plan and subsequently recalculate the radiation treatment plan, so these images necessarily must be stored on a memory, p. 668, col. 2, paragraph 1); and a processor for: performing the process steps as discussed in claims 1-6 above (The method taught by Di Yan et al. necessarily comprises a processor to store the CT images acquired in the memory and to perform the image analysis algorithm. Di Yan et al. teaches that 3D treatment planning software and finite element method software was employed to perform the process, which necessarily must be run using a processor, p. 669, col. 2, paragraph 2; see discussions above for claims 1-6).

Regarding **claim 11**, Di Yan et al. teaches a computer program for a radiation therapy planning device, wherein a processor of the radiation therapy device performs the process steps as discussed in claims 1-6 when the computer program is executed on the processor (The method taught by Di Yan et al. necessarily comprises a processor to store the CT images acquired in the memory and to perform the image analysis algorithm. Di Yan et al. teaches that 3D treatment planning software and finite element method software was employed to perform the process, which necessarily must be run using a processor, p. 669, col. 2, paragraph 2; see discussions above for claims 1-6).

Regarding **claim 12**, Di Yan et al. teaches a method wherein the second surface mesh and the third surface mesh result from applying the same surface model (The surface mesh model for the second and third meshes is the same because generating and applying a surface mesh necessarily includes adapting a surface mesh to an object of interest in the image. Therefore the mesh that is generated and the mesh that is applied to the surface of interest is the same, p. 667, col. 1, paragraph 1).

Regarding **claim 13**, Di Yan et al. teaches a device comprising a processor wherein the second surface mesh and the third surface mesh result from applying the same surface model (The surface mesh model for the second and third meshes is the same because generating and applying a surface mesh necessarily includes adapting a surface mesh to an object of interest in the image. Therefore the mesh that is generated and the mesh that is applied to the surface of interest is the same, p. 667, col. 1, paragraph 1; see discussion for claim 8 above).

Regarding **claim 14**, Di Yan et al. teaches a method for adapting a dose distribution of a radiation therapy plan comprising: adapting a first surface mesh to an object of interest in a first image (reference image, p. 667, col. 1, paragraph 1); adapting a second surface mesh to the object of interest in a subsequent image (second image is k treatment CT image that is analyzed with the same volumetric mesh procedure as the first image, p. 668, col. 2, paragraph 1); deforming a volumetric model of the object of interest based on a difference between the first and second surface meshes (calculates displacement and new position of the organ based on a subsequent image, which is volumetric organ deformation, p. 668, col. 1, paragraph 3).

Regarding **claim 15**, Di Yan et al. teaches that the subsequent image is acquired prior to a radiation therapy treatment (kth treatment image is necessarily acquired prior to the following radiation therapy treatment, p. 668, col. 2, paragraph 1).

Regarding **claim 16**, Di Yan et al. teaches that the subsequent image is acquired prior to a predetermined interval of radiation therapy treatments (The kth treatment image is necessarily acquired prior to a predetermined interval of radiation therapy treatments because the kth treatment image is acquired prior to the remainder of the following radiation therapy treatments, p. 668, col. 2, paragraph 1).

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carrie Harris whose telephone number is (571) 270-7483. The examiner can normally be reached on Monday - Friday from 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/C. H./
Examiner, Art Unit 3735